UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,126	08/23/2006	Yehudit Natan	27586U	5429

20529 7590 06/26/2009

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
06/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,126	NATAN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-64 and 66-93* is/are pending in the application.

4a) Of the above claim(s) *67-91 and 93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-64,66 and 92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of Group I, claims 54-72 and 86-92, in the reply filed on April 6, 2009 is acknowledged. The traversal is on the ground(s) that the groups of claims all share a special technical feature, i.e. the biological material; that the examiner has not shown a serious burden in examining all of the claims; and that Applicants have paid a filing fee for examination of all claims. This is not found persuasive because: (1) The claims do not share a special technical feature, as shown by the prior art references applied below, and as shown by the references cited in the international search report and designated X or Y references against claims 21-34 and 53. Biological materials, e.g., red blood cells, white blood cells, mononuclear cells, umbilical cord blood cells, hematopoietic stem cells, and bacteria, can not constitute a special technical feature linking all of the claims, because biological materials are known in the prior art. If a technical feature is taught or rendered obvious by the prior art, by definition the technical feature does not define a contribution which the claims make over the prior art. See MPEP 1893.03(d), page 1800-209, column 1, first full paragraph (Rev. 7, July 2008). (2) Because of the lack of a special technical feature among the claimed inventions, there would be a serious burden on the examiner in searching all of the claimed inventions. A search of freeze drying methods is not co-extensive with a search of biological materials and/or with a search of methods of forming solutions. (3) Payment of a filing fee does not prevent the Office from imposing a restriction requirement and/or from finding a lack of unity of invention. Payment of a filing fee does not grant Applicants the right to have any number of inventions examined in a single application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 73-85 and 93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 6, 2009.

Applicant's election without traverse of the species hematopoietic stem cells in the reply filed on April 6, 2009 is acknowledged. Applicants state at page 12 of their response that claims 67-72 and 86-91 read on the elected species. However, these claims are drawn to methods of preserving red blood cells, which are different than the elected species.

Claims 67-72 and 86-91 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 6, 2009.

2. The declaration filed August 23, 2006 does not explicitly identify the city and either state or foreign country of residence of each inventor. The Office has assumed that the city and foreign country given in each inventor's Post Office Address are the inventors' residences. If this assumption is incorrect, correct residence information may be provided in either an application data sheet or a supplemental oath or declaration.

The declaration filed August 23, 2006 gives an incorrect filing date for provisional application 60/577,210. The correct filing date for this provisional application is June 7, 2004, i.e. 06/07/2004. However, because the provisional application is otherwise correctly identified, and because there is no requirement that provisional applications which form the basis for a claim for priority under 35 U.S.C. 119(e) be listed in an oath or declaration under 37 CFR 1.63, the declaration is acceptable.

3. The abstract of the disclosure is objected to because at line 10 of the amended Abstract, "MNC" is repeated. It is believed that the second occurrence of "MNC" should be changed to "HSC", i.e. the elected species. Also, the Abstract should be in the form of a single paragraph. Correction is required. See MPEP § 608.01(b).

4. It is noted that this application appears to claim subject matter disclosed in prior Application Nos. 60/540,557, filed February 2, 2004, and 60/577,210, filed June 7, 2004. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). See MPEP § 201.11.

5. Claims 61 and 92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the macromolecule" in claim 61. It is believed that claim 61 should instead depend upon claim 60. The phrase "essentially free" in claim 92, step (a), is indefinite because the phrase is given two different conflicting definitions in Applicants' specification. See page 12, lines 9-20, and page 16, lines 12-13. It can not be determined which definition of the phrase provided by Applicants is controlling.

6. Claims 54-64 and 66 are objected to because of the following informalities: In claim 54, step (a), the phrase "comprising one or more polyphenols" should be moved so that it occurs immediately after "preservation solution". Appropriate correction is required.

7. Applicant is advised that should claim 63 be found allowable, claim 64 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 64 recites that the cryopreservation is freezing, a limitation already present in independent claim 54 and in claim 63, and that the cryopreservation solution is a freezing solution, a limitation inherently present in independent claim 54 (in which the preservation solution is subject to freezing) and in claim 63 (in which the preservation solution is a cryopreservation solution).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

9. Claims 54-59, 63, and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Gen (U.S. Patent Application Publication 2002/0119946). Gen teaches adding an aqueous saline solution comprising polyphenols to a protein such as insulin, interferon-alpha, EGF, and protein allergens, or to DNA, and then freeze-drying the mixture. The polyphenols can be epigallocatechin gallate and can be extracted from green tea. The polyphenol solutions are not described as comprising glycerol or DMSO. See, e.g., the Abstract; paragraphs [0009] - [0011]; Examples 1-3, 5, and 6. The proteins and DNA of Gen correspond to Applicants' biological material. The time period which occurs between Gen's freeze-drying step and Gen's subsequent use of the complexes corresponds to Applicants' storing under appropriate storing conditions. Because the polyphenols of Gen are dissolved in aqueous saline solution prior to complexing and freeze-drying, inherently the freeze drying of Gen will occur at a temperature below $0^{o}C$, because the presence of solutes depresses the freezing point of a solution below that of the solvent. Sufficient evidence of similarity is deemed to be present between the method of Gen and Applicants' claimed method to shift the burden to Applicants to provide evidence that the claimed method is unobviously different than that of Gen.

10. Claim 92 is rejected under 35 U.S.C. 102(b) as being anticipated by Wiggins et al (U.S. Patent Application Publication 2002/0177116). Wiggins et al teach lyophilization of eukaryotic cells using a preservation solution which does not comprise any polyalcohol. See, e.g., Example 15.

11. Claims 54-56, 58-60, 62-64, and 66 are rejected under 35 U.S.C. 103(a) as being obvious over Mann et al (U.S. Patent Application Publication 2003/0059338). Mann et al teach combining thrombin with epicatechin and bovine serum albumin, lyophilizing the mixture, and then subjecting the lyophilized mixture to gamma irradiation for purposes of sterilization. There is no description or indication of glycerol or DMSO being combined with the thrombin. See, e.g., the Abstract and paragraph [0098]. The thrombin of Mann et al corresponds to Applicants' biological material. The bovine serum albumin of Mann et al corresponds to Applicants' macromolecule. During the time after lyophilization, up to and after the gamma irradiation step, the lyophilized mixture of Mann et al inherently is being stored by Mann et al. Note that Applicants' claims do not require any particular storing procedures, storing times, or storing conditions. Mann et al do not teach combining epicatechin and bovine serum albumin in the form of a solution with the thrombin. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to combine epicatechin and bovine serum albumin in the form of a solution with the thrombin, because it is easier to mix ingredients in solution form, because the solvent would be removed by the lyophilization step and thus would not be expected to interfere with the final product, and because use of a solvent for the epicatechin and bovine serum albumin would not appear to result in any different properties for the lyophilized mixture. More generally, Mann et al teach sterilization of biological materials including stem

cells, red blood cells, white blood cells, and monocytes, in which the biological materials are combined with a flavanoid/flavonol stabilizer including epigallocatechin gallate and an optional additional stabilizer including trehalose, and wherein the residual solvent content of the biological material is reduced prior to irradiation, such as by lyophilization. The biological materials, including the lyophilized biological materials, are stored under vacuum or in an inert atmosphere prior to irradiation. See, e.g., paragraphs [0027], [0031], [0036], [0037], [0058], [0059], [0078], and [0081]. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to subject the biological materials including stem cells, red blood cells, white blood cells, and monocytes of Mann et al to lyophilization, storage, and irradiation in the presence of stabilizers including epigallocatechin gallate and trehalose because Mann et al teach the desirability of sterilizing such biological materials, and teach the utility of combinations of treatments, i.e. use of a stabilizer, lyophilization, and storage under vacuum prior to irradiation, in order to sterilize the biological materials. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to combine the stabilizers of Mann et al in the form of a solution with the biological material to be sterilized, because it is easier to mix ingredients in solution form, because the stabilizer solvent would be removed by the lyophilization step and thus would not be expected to interfere with the final product, and because use of a solvent for the stabilizers would not appear to result in any different properties for the lyophilized mixture.

12. Claims 54-61, 63, and 64 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 03/099040. The WO Patent Application ‘040 teaches combining white wine vinasses, maltodextrin, blueberry extract, and green tea extract, and freeze drying the

mixture. See Example 2. The white wine vinasses and blueberry extract of the WO Patent Application '040 correspond to Applicants' biological material; and the maltodextrin of the WO Patent Application '040 corresponds to Applicants' macromolecule. During the time after freeze drying, up until the lyophilized mixture's use as a dietary supplement, the freeze dried mixture of the WO Patent Application '040 inherently is being stored by the WO Patent Application '040. Note that Applicants' claims do not require any particular storing procedures, storing times, or storing conditions. The WO Patent Application '040 does not teach combining maltodextrin and green tea extract in the form of a solution with the white wine vinasses and blueberry extract. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to combine maltodextrin and green tea extract in the form of a solution with the white wine vinasses and blueberry extract, because it is easier to mix ingredients in solution form, because the solvent would be removed by the lyophilization step and thus would not be expected to interfere with the final product, and because use of a solvent for the maltodextrin and green tea extract would not appear to result in any different properties for the freeze dried mixture. The WO Patent Application '040 does not teach a method in which dextran is combined with a wine vinasse and the resulting mixture is freeze dried. However, the WO Patent Application '040 teaches that dextran is a bioavailability promoter which is useful for combining with wine vinasses, and that bioavailability promoters in general can be combined with the wine vinasses prior to freeze-drying. See, e.g., page 3, line 27 - page 4, line 8, and page 5, lines 8-9. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute dextran for maltodextran in Example 2 of the WO Patent Application '040 as

modified above, because substitution of one known functional equivalent for another with only the expected retention of function, i.e. bioavailability promotion, is prima facie obvious.

13. Oliver et al (U.S. Patent No. 5,897,987) is cited as art of interest, teaching a method of cryopreserving somatic cells using a medium comprising arabinogalactan which can comprise polyphenol as an impurity. Additional cryoprotective agents may be included in the medium. See, e.g., column 3, lines 35-43. However, the disclosure of Oliver et al is limited to freezing methods, which does not teach or render obvious the freeze-drying/lyophilizing which is required by Applicants' claims.

The European Patent Application 1,057,405, cited in the International Search Report, has been carefully considered but is not deemed to anticipate or render obvious the instant claims. The European Patent Application '405 teaches using the same preservation solutions comprising polyphenols claimed by Applicants to preserve the same biological materials claimed by Applicants. However, the European Patent Application '405 uses such preservation solutions in order to avoid freezing of the preserved biological materials (see, e.g., paragraph [0015]) whereas the instant elected claims have been amended so as to require freeze-drying.

14. The references cited in the International Search Report dated August 4, 2005 have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
June 27, 2009